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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,576	08/20/2003	Connie Sanchez	05432/100M919-US5	5194

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EXAMINER	
CHONG, YONG SOO	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/644,576	SANCHEZ ET AL.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/6/2007 has been entered.

Claim(s) 1-19 have been cancelled. Claim(s) 20-37 are pending and examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejection(s) of the last Office Action are maintained for reasons of record and repeated below for Applicant's convenience.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 20-37 are rejected under 35 U.S.C. 103(a) as being obvious over Boegesoe et al. (US Patent 4,943,590) and further in view of Audia et al. (US Patent 5,846,982) and Shaller et al. (J. Neuropsychiatry and Clinical Neurosciences, 11:4, Fall 1999, abstract).

The instant claims are directed to a method of treating attention deficit hyperactivity disorder (ADHD) by administering escitalopram.

Boegesoe et al. teach the method of treating depression in a patient with the (+) enantiomeric form of citalopram, otherwise referred to as escitalopram, by inhibiting the uptake of serotonin (col. 1, lines 9-26). Acceptable pharmaceutical salts of escitalopram include oxalate (col. 1, lines 29-42). What's more, daily dosage of escitalopram is disclosed to be from 5 to 50 mg (col. 8, lines 55-60).

However, Boegesoe et al. fail to disclose a method of specifically treating attention deficit hyperactivity disorder with escitalopram.

Audia et al. teach that attention deficit hyperactivity disorder (col. 53, line 7) can be treated with compounds that inhibit serotonin reuptake (abstract).

Moreover, Shaller et al. teach that attention deficit hyperactivity disorder increases one's risk for both major depression and an anxiety disorder by approximately 25%.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to administer patients suffering from attention deficit hyperactivity disorder an effective amount of escitalopram, because both attention deficit hyperactivity disorder and depression are treatable by inhibiting the uptake of serotonin. Treating a patient suffering from depression with escitalopram will also treat the same patient who is suffering from attention deficit hyperactivity disorder.

A person of ordinary skill in the art would have been motivated to administer escitalopram to patients suffering from attention deficit hyperactivity disorder, because of the expectancy of the same amount of success when treating patients suffering from depression with escitalopram and since both disorders are treatable by inhibiting serotonin reuptake. Moreover, since Shaller et al. discloses that the risk of depression is increased in attention deficit disorder patients, the motivation to administer escitalopram to ADHD patients is because of the reasonable expectancy of decreasing the risk of depression.

Response to Arguments

Applicant argues that Schaller teaches away from the presently claimed method by disclosing that ADHD must be treated separately from depression and that an SSRI is not effective in treating ADHD. Specifically, Applicant argues that when sertraline, an SSRI, was administered to an ADHD patient, improvement was shown, however, panic attacks continued. Then, clonazepram, not an SSRI, was administered and showed a better BAI score in addition to a cease in panic attacks for two months. Applicant argues that "despite his improvement, the patient still met criteria for adult ADHD." As to the ADHD, the patient only improved when treated with both clonazepram and Ritalin. Therefore, Applicant argues that SSRIs are not effective for treating ADHD.

This is not found persuasive because Applicant cannot make such definitive conclusions based on a single case report of a 38-year-old man with depression. At the outset, the Schaller reference was only used to show that ADHD increases one's risk for major depression. Applicant's arguments directed toward sertraline have nothing to do

with the obviousness rejection since sertraline was not claimed. Furthermore, there is no mention in the Schaller reference that SSRI are not effective in treating ADHD or depression. In fact, sertraline partially improved the BAI score of the patient from 28 to 20. Examiner reminds Applicant that the standard for obviousness is not absolute, but rather a reasonable expectation of success.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to administer patients suffering from attention deficit hyperactivity disorder an effective amount of escitalopram, because both attention deficit hyperactivity disorder and depression are treatable by inhibiting the uptake of serotonin. Treating a patient suffering from depression with escitalopram will also treat the same patient who is suffering from attention deficit hyperactivity disorder. Moreover, since Shaller et al. discloses that the risk of depression is increased in attention deficit disorder patients, the motivation to administer escitalopram to ADHD patients is because of the reasonable expectancy of decreasing the risk of depression.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER